

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

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| <b>IN RE: ETHICON, INC., PELVIC<br/>REPAIR SYSTEM PRODUCTS<br/>LIABILITY LITIGATION</b>                               | <b>Master File No. 2:12-MD-02327</b><br><br><b>MDL 2327</b><br><br><b>JOSEPH R. GOODWIN</b><br><b>U.S. DISTRICT JUDGE</b> |
| <b>THIS DOCUMENT RELATES TO:</b><br><br><b>ETHICON WAVE 5 CASES LISTED<br/>IN EXHIBIT A TO PLAINTIFFS’<br/>MOTION</b> |                                                                                                                           |

**MEMORANDUM IN OPPOSITION TO PLAINTIFFS’ MOTION TO EXCLUDE  
CERTAIN TESTIMONY OF MARSHALL D. SHOEMAKER, M.D.**

Dr. Shoemaker is a gynecologist with board certification in Obstetrics and Gynecology. *See* Marshall Shoemaker, M.D., Curriculum Vitae (“Shoemaker CV”) [Dkt. 4328-8]; Expert Report of Marshall Shoemaker, M.D. Gynemesh PS, Prolift, Prolift+M, and Prosima (“Prolift Report”) [Dkt. 4328-2]; Expert Report of Marshall Shoemaker, M.D. re TVT, TVT-O, TVT Abbrevio, and TVT Exact (“TVT Report”) [Dkt. 4328-3]. Under Rule 702, he is without question an expert in the fields of pelvic medicine generally and in the surgical treatment of pelvic organ prolapse and stress urinary incontinence specifically.

Dr. Shoemaker prepared two general reports for Wave 5—one addresses the pelvic organ prolapse medical devices manufactured by Ethicon, Inc. (Gynemesh PS, Prolift, Prolift+M, and Prosima); the other addresses the stress urinary incontinence medical devices manufactured by Ethicon, Inc. (TVT, TVT-O, TVT Abbrevio, and TVT Exact).

Plaintiffs do not challenge the overwhelming majority of Dr. Shoemaker’s general opinions. Rather, Plaintiffs only seek to limit Dr. Shoemaker’s testimony on two points: (1) his opinions about the devices’ IFUs and Surgeon’s Resource Monograph, and (2) his opinions

about the physical properties of Ethicon's Prolene mesh as it interacts with the human body after implantation. Plaintiffs assert a qualifications challenge and a methodology challenge to each of these two opinions. Neither category of challenge is availing.

**First**, Dr. Shoemaker is qualified to offer his IFU/Monograph opinions. Dr. Shoemaker opines that the IFUs and Monograph adequately apprise surgeons of the risks associated with the subject devices. To arrive at this opinion, Dr. Shoemaker relied on his clinical experience with the devices and conducted a review of the medical literature to determine the risks associated with the devices. Then, he compared those risks to the warnings contained in the IFUs and Monograph and opined that those risks are adequately addressed in the IFUs and Monograph. As a board certified surgeon in obstetrics and gynecology who has performed literally thousands of prolapse and SUI surgeries using the subject devices, Dr. Shoemaker is imminently qualified to offer this opinion. To the extent that Plaintiffs argue that Dr. Shoemaker needs some additional qualifications to opine about what should or should not be included in a medical device IFU, Plaintiffs misapprehend the nature of Dr. Shoemaker's testimony. He has not and will not opine about what should or should not be included in the IFUs; rather, his opinion is that the risks associated with these devices are adequately identified in the IFUs.

**Second**, Dr. Shoemaker's methodology in arriving at his IFU/Monograph opinions is reliable. Dr. Shoemaker relied on both his clinical experience and his medical literature review. Plaintiffs argue that there is medical literature that is contrary to Dr. Shoemaker's opinions, that he failed to give sufficient weight, and that his medical review failed to identify certain articles that were unrelated to transvaginal mesh. Plaintiffs' arguments all go to the weight to be given to Dr. Shoemaker's opinions by the trier of fact—not their admissibility. Thus, these challenges should be reserved for cross-examination.

**Third,** Dr. Shoemaker is qualified to opine about how Prolene mesh interacts with the human body *in vivo*. Plaintiffs argue that Dr. Shoemaker cannot offer “design” opinions because he has not been involved in the process of designing any transvaginal mesh products. Plaintiffs’ efforts to shoe horn Dr. Shoemaker’s physical properties opinions as “design process” opinions as being relevant to a design defect claim miss the mark entirely. Dr. Shoemaker is not opining about the process by which Ethicon developed and designed these devices. His opinions are limited to how the polypropylene mesh in these devices (i.e., the physical properties of the mesh) interacts with the human body. As a board certified surgeon who has implanted thousands of these devices in women and subsequently followed his patients post-implant, Dr. Shoemaker is more than qualified to discuss how the products interact with the human body.

**Finally,** Dr. Shoemaker’s methodology in arriving at his opinions regarding how the physical properties of Prolene interact with the human body is based on a reliable methodology. Dr. Shoemaker relied on his clinical experience, his review of the scientific peer-reviewed medical literature, and the same type of methodology found in this literature. Plaintiffs’ attacks on his methodology in fact go to the weight to be given, not the admissibility of, his opinions.

For these reasons, Plaintiffs’ motion to limit Dr. Shoemaker’s testimony should be denied.

### **LEGAL ARGUMENT AND AUTHORITIES**

Plaintiffs ostensibly make only two challenges to Dr. Shoemaker, arguing that he is unqualified to offer opinions about the IFUs and that he is unqualified to offer design opinions. Upon review, Plaintiffs’ Brief [Dkt. 4329] reads like a cross-examination rather than a *Daubert* motion. Peppered throughout their two overarching contentions, Plaintiffs also assert various methodology challenges. Ethicon addresses the enumerated qualification challenges first. Then

Ethicon will address Plaintiffs' random methodology contentions contained within the qualifications challenges.

**I. Dr. Shoemaker Is Qualified to Opine on the IFUs and Surgeon's Resource Monograph.**

Dr. Shoemaker opines that Ethicon's IFUs, Surgeon's Resource Monograph, and the common knowledge of pelvic floor surgeons apprise surgeons of the risks associated with the various Ethicon products. To arrive at this opinion, Dr. Shoemaker relied on his decades of experience implanting these devices and his extensive review of the medical literature. Throughout the body of his reports, Dr. Shoemaker identifies the risks associated with non-mesh prolapse and SUI surgery. Likewise, he identifies the risks associated with mesh prolapse and SUI surgery. He compares the non-mesh risks to the mesh risks and identifies which risks are unique to mesh surgery. Then, Dr. Shoemaker compares those risks to the language of the IFUs and Monograph. Ultimately, he concludes that the Ethicon adequately warned the intended users of these products—i.e., surgeons like Dr. Shoemaker—of the risks unique to these devices. Dr. Shoemaker's qualifications to engage in this type of analysis are his education, training, and decades of experience in the field of pelvic reconstruction surgery and SUI repair.

Plaintiffs argue that Dr. Shoemaker is unqualified to offer this opinion because he lacks training and experience with the FDA 510(k) approval process and he has not been involved in the creation of a device IFU. *See* Pls.' Br. [Dkt. 4329] at 4. Additionally, Plaintiffs contend that Dr. Shoemaker's clinical experience using the subject products and his review of the medical literature does not qualify him to offer any opinions about the IFUs for these products. *See id.* at 4-5. Plaintiffs' arguments are contrary to this Court's holdings.

First, Plaintiffs' argument that Dr. Shoemaker's opinions are inadmissible because he did not rely on FDA regulations rests entirely on the supposition that expertise in FDA regulations

related to requirements for IFUs is mandatory for these opinions. Yet, the job of an expert witness is to identify the pertinent facts of the case and opine about their relevance related to the factual allegations of the Master Complaint. *See* Fed. R. Evid. 702 (a) (“help the trier of fact to understand the evidence or to determine a fact in issue”), (b) (“the testimony is based on sufficient facts or data”). It is not the expert’s job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2014 WL 186872, at \*20 (S.D. W. Va. 2014) (citing *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)). The key question here is whether Dr. Shoemaker’s testimony is based on his scientific, technical, or other specialized knowledge, skill, experience, training, and professional education, thereby enabling him to help the trier of fact to understand the evidence or to determine a fact in issue, and not whether he himself could articulate or opine about the governing legal standard. If he had attempted to do that, his testimony would have been excluded.

Dr. Shoemaker’s IFU opinions and qualifications and his IFU opinions are similar to those previously found to be admissible by this Court. In *Trevino v. Boston Scientific Corp.*, 2:13-CV-01617, 2016 WL 2939521, at \*13-14 (S.D. W. Va. May 19, 2016), the defendant sought to exclude the warnings testimony of plaintiff’s urogynecologist Bobby L. Shull, M.D. There, the defendant argued that Dr. Shull was not qualified to opine on the adequacy of the IFU because Dr. Shull “is not an expert in the regulations or standards that govern [IFUs]; he has never advised a company on a[n IFU]; he is unfamiliar with the industry process governing [IFUs]; and he has not even performed a literature search relating to DFUs.” *Id.* at \* 13. The plaintiff noted that Dr. Shull had not been designated to offer any opinions regarding the manner by which the defendant developed the IFU or the regulatory requirements applicable to IFUs. *Id.* Instead, Dr.

Shull was only offered “to opine on the completeness and accuracy of the [product’s] warnings from a clinical perspective.” *Id.* at \*40-41. This Court held that Dr. Shull’s testimony along these lines would be admissible:

Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison. *See, e.g., Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at \*34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product’s DFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at \*11 (S.D. Ill. Dec. 16, 2011) (“[D]octors are ‘fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] ... and to compare that knowledge with what was provided in the text of labeling and warnings ....’” (quoting *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at 11 (E.D. Pa. June 20,2000))). I also find that Dr. Shull’s forty years of experience, along with his evaluation of medical literature forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S. at 156 (stating that “an expert might draw a conclusion from a set of observations based on extensive and specialized experience”).

*Id.* Just like Dr. Shull, Dr. Shoemaker is relying on his years of clinical experience and his review of the medical literature to identify the risks associated with the devices and opines that the respective IFUs and Monograph did warn physicians of the risks.

As discussed above, the legal principle that controls here is that a device manufacturer’s duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j (seller “is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users.”); *see also* RESTATEMENT (SECOND) OF THE LAW

OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 ( Va. 2009) (adopting “sophisticated user” defense in §388).

This limitation on the duty to warn is recognized in medical device cases as well. There is no duty to warn of risks that are commonly known by implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers “not well known to the medical community”). In fact, the FDA regulations recognize that risk-related information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.” 21 C.F.R. §801.109(c) (emphasis added).

Here, the devices’ IFUs restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See, e.g.*, Ex. A, Prolift IFU (ETH.MESH.02341459) at 6 (“Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.”); Ex. B, Prolift+M IFU (ETH.MESH.01595615) at 2 (“Physicians should have experience in management of complications resulting from procedures using surgical mesh. . . . Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT+M™ Systems.”); Ex. C, TVT-O IFU at 1 (ETH.MESH.00860240) (“This package insert is designed to provide instruction for use of the GYNECARE TVT\* Obturator System . . . . It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence

and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device.”).

Again, the important question with respect to Plaintiffs’ failure to warn claim is: what “hazards” and are “commonly known” to surgeons familiar with pelvic surgery, including surgery to address pelvic organ prolapse and SUI? That is precisely the opinion reached by Dr. Shoemaker. He reviewed the risks associated with non-mesh surgical repair. *See* Prolift Report [Dkt. 4328-2] at 5-10; TVT Report [Dkt. 4328-3] at 5-8. Dr. Shoemaker then examined the risks associated with mesh surgical repair. *See* Prolift Report [Dkt. 4328-2] at 10-33; TVT Report [Dkt. 4328-3] at 8-24. And he ultimately concludes that the risks specific to the devices were discussed in the IFU and Monograph. *See* Prolift Report [Dkt. 4328-2] at 33-37; TVT Report [Dkt. 4328-3] at 28-31. Dr. Shoemaker’s scientific, technical, or other specialized knowledge, skill, experience, training, and professional education, enable him to help the trier of fact to understand the evidence or to determine the facts related to this issue.

Ethicon is mindful of the Court’s Wave 1 rulings that experts without additional regulatory expertise on product labeling and compliance cannot testify “about what an IFU should or should not include.” *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4557036, at \*3. But that is not what Dr. Shoemaker is doing here. He will not offer opinions about what should or should not be included in an IFU. Rather, through his own experience and his examination of the medical literature, he (1) identifies the risks associated with non-mesh pelvic floor surgery and SUI surgery, (2) identifies the risks associated with mesh pelvic floor surgery and SUI surgery, (3) compares the non-mesh risks to the mesh risks to determine which, if any, are unique to the mesh surgeries, and (4) offers his opinion as to whether the IFUs and Monograph warned physicians of the risks unique to the mesh surgeries.

Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Shoemaker's conclusion can be addressed on cross-examination. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D. W. Va. 2014).

## **II. Dr. Shoemaker Employed a Reliable Methodology in Arriving at His IFU Opinions**

Strewn amongst Plaintiffs' qualifications challenge, Plaintiffs appear to assert four challenges to Dr. Shoemaker's methodology. Plaintiffs contend that his methodology is unreliable because (1) there is medical literature contrary to Dr. Shoemaker's opinions, (2) there is medical literature that Dr. Shoemaker did not include in his report, (3) Dr. Shoemaker alleged misrepresented the holdings of "multiple studies," and (4) Dr. Shoemaker relied on his clinical experience.

### **A. The Existence of Contrary Medical Literature Does Not Render an Expert's Opinion Unreliable**

Plaintiffs argue that Dr. Shoemaker's IFU opinions are unreliable because there is medical literature that is purportedly contrary to his opinions. Specifically, Plaintiffs argue that there is "[c]onflicting evidence and scientific viewpoints" on the issue of "mesh shrinkage." *See* Pls.' Br. at 5. They also argue that Dr. Shoemaker "chose to rely on studies that he essentially 'cherry-picked' to support his opinions." *Id.* at 9. Plaintiffs cite to only one study that purportedly contained contradictory information and that Dr. Shoemaker did not consider reliable: "Mesh Related and Intraoperative Complications of Pelvic Organ Prolapse Repair." *See* Pls.' Br. at 8-9.

What Plaintiffs do not say, however, is that they specifically asked Dr. Shoemaker about this article in his deposition and he explained his basis for disagreeing with the study:

Q. So these authors are describing mesh shrinkage as one of the most frequent complications associated with mesh usage for POP; correct?

A. That's what this sentence states, yes.

Q. Do you disagree based upon your review of the literature that it's one of the most common complications?

A. I have not seen that as one of the most common. In fact, it looks like it says here .3 percent or it's 1 percent. I'm trying to read what it says. It's a low number, it looks like. Out of 677 patients, it looks like it's a low number.

...

Q. Now, this paper is in your reliance list. But that information and the description of mesh shrinkage as being one of the most serious complications is nowhere in your expert report, is it?

A. Correct, correct. Because --

...

A. Let me explain that. It's talking about five cases in this situation. And I'm not sure how you get urethral obstruction with a mesh case that was put in correctly. And also it talks about the fixation arms. I'm not sure how this was placed that it would cause this kind of situation. Maybe if it was not placed tension free, maybe that caused some of the -- when it scarred, it made the contraction worse -- the scarring of the vagina worse and caused the pain. Because I don't know how you get a urethral obstruction from a vaginal mesh. I just don't see how that could happen, unless they put it in the urethra incorrectly. There's no way it could affect the urethra, in my opinion. In fact, the mesh shouldn't be placed that far. It should stop at the urethrovesical junction, so there shouldn't be any mesh near the urethra, unless it was from a sling. But it doesn't mention that.

Shoemaker 7/21/17 Depo. [Dkt. 4328-4] 150:16-151:3, 152:1-152:24.

While Plaintiffs are correct on the limited point that an expert must take into account and consider contrary evidence, Plaintiffs fail to adduce any evidence or plausible argument that Dr.

Shoemaker failed to consider this article. It is cited in his reliance list as an article that he reviewed in forming his opinions, and at his deposition he explained his scientific bases for disagreeing with the conclusion of this article. The fact that Plaintiffs believe Dr. Shoemaker should give the article greater weight than he does goes to the weight of his testimony, not its admissibility.

**B. An Expert Need Not List Every Piece of Literature for His Methodology to Be Reliable**

Plaintiffs espouse the untenable position that an expert's methodology cannot be deemed reliable unless the expert lists in his report every article, paper, and publication that exists in relation to the subject matter. Specifically, Plaintiffs argue that Dr. Shoemaker did not identify a study involving hernia mesh (not transvaginal mesh) and that his failure to do so renders his IFU opinions unreliable. *See* Pls.' Br. [Dkt. 4329] at 6-8. Plaintiffs cite no case law or other authority for this novel legal proposition; this absence of citation is likely due to the fact that Plaintiffs' argument is contrary to the law and to this Court's prior holdings.

The Court rejected a similar argument in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521 (S.D. W. Va. May 19, 2016). The plaintiff in that case challenged the competence of defense expert Stephen Badylak, M.D., to testify about the safety and efficacy of polypropylene mesh devices on the basis that Dr. Badylak had “‘admitted that he ha[d] not performed a ‘comprehensive review’ of the literature related to [the defendant’s] devices.” *Id.* at \*40. The Court, however, noted that Dr. Badylak’s report demonstrated that he “reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices,” and that “[i]f there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.” *Id.*; *see also Bethune v. Boston Sc. Corp.*, 2016 WL

2983697, at \*4 (S.D. W. Va. May 20, 2016) (“[t]o the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis’s opinions, not their admissibility”; “[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions”).

Plaintiffs’ arguments here against Dr. Shoemaker are even less tenable. Dr. Shoemaker reviewed more than 900 articles in reaching his opinions. Plaintiffs challenge him with a single article—an article that is not about transvaginal mesh, let alone the devices at issue in this litigation. Neither the law nor the rules of evidence or civil procedure require an expert witness to review each and every study, article, and paper published on a given topic or to explain in his report why he has elected not to rely upon a certain study, article, or paper. Plaintiffs may question Dr. Shoemaker about the documents upon which he relied and his reasons for not relying on others. But this is a question for cross-examination, not for the exclusion of his opinions under *Daubert*.

**C. Plaintiffs’ Claim that Dr. Shoemaker Misrepresented the Studies Relied Upon Are Unfounded**

Plaintiffs make the unsupported contention that Dr. Shoemaker’s statements about “multiple studies” cited in his reports “differ from what the actual studies report.” Pls.’ Br. [Dkt. 4329] at 10. Plaintiffs do not identify these purported “studies.” Instead, they materially misquote a single statement of Dr. Shoemaker in his Prolift Report about one particular article.

To this end Plaintiffs contend that Dr. Shoemaker cited the 2016 Cochrane Review for the proposition that “the use of a permanent polypropylene mesh demonstrates lower rates of ... prolapse on examination in contrast to native tissue repair.” Pls.’ Br. [Dkt. 4629] at 10. Dr. Shoemaker actually wrote this: “[T]he use of permanent polypropylene mesh demonstrates lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination in

contrast to native tissue repair.” Prolift Report [Dkt. 4328-2] at 24 (differences between Plaintiff’s quotation and Dr. Shoemaker’s report underlined).

For its part, the 2016 Cochrane review states exactly what Dr. Shoemaker wrote in his Prolift Report (not Plaintiffs’ altered quotation): “[P]ermanent mesh is associated with lower rates of awareness of prolapse, repeat surgery for prolapse, and prolapse on examination that native tissue repair.” *See* Ex. D, Excerpts from Maher, Christopher, et al., Transvaginal Mesh or Grafts Compared with Native Tissue Repair for Vaginal prolapse, Cochrane Database of Systematic Reviews (2016) at 29.

Dr. Shoemaker cited the 2016 Cochrane Review for one of the very specific findings that it made. Plaintiffs’ argument that the 2016 Cochrane Report somehow differed from Dr. Shoemaker’s statement in his report is entirely unsustainable.

**D. An Expert Is Entitled to Rely on His Clinical Experience in Combination with a Literature Review**

Plaintiffs erroneously contend throughout their brief that an expert cannot rely on his clinical experience to form his opinions. *See* Pls.’ Br. [Dkt. 4329] at 5, 8. The Court has repeatedly held that an expert can offer IFU-opinions of the type advanced by Dr. Shoemaker where the expert relies on his clinical experience and a medical literature review. *See, e.g., Trevino*, 2016 WL 2939521, at \*13-14. Plaintiffs do not address, much less attempt to distinguish, these prior rulings of the Court, and their contention should be rejected yet again.

**III. Dr. Shoemaker Is Qualified to Discuss the Design Properties of the Subject Products**

**A. Dr. Shoemaker Is Not Offering Any Design Process Opinions**

Plaintiffs’ attack on Dr. Shoemaker’s “design” opinions is similarly unsustainable and is the latest example of what the Court deemed is a “plague” of “confusion about what constitutes a design opinion.” *In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, Mem. Op. & Order

(*Daubert* Motion re: Melvin Anhalt, M.D.), MDL No. 2327, 2016 WL 4493585, at \*3 (S.D. W. Va. Aug. 25, 2016). Plaintiffs contend Dr. Shoemaker cannot offer “design” opinions because he does not have a background in “designing mesh devices and has limited knowledge of the design process.” Pls.’ Br. [Dkt. 4329] at 12. It is clear from the context of the challenge that Plaintiffs are seeking to exclude all opinion testimony from Dr. Shoemaker about the products’ design (i.e., the physical properties of the mesh) because of his personal lack of familiarity with the process by which Ethicon went about designing the devices. *See* Pls.’ Br. [Dkt. 4329] at 12-16. For example, Plaintiffs cite testimony that Dr. Shoemaker was not involved in the design of any of the Ethicon devices and that he has limited knowledge about the design process actually employed for the subject devices. *See id.*

Dr. Shoemaker is not offering any such opinions about the design process. *See generally* Prolift Report [Dkt. 4328-2]; TVT Report [Dkt. 4328-3]. Rather, Dr. Shoemaker’s opinions relate to the physical properties of the devices themselves—the finished product, not the process. *See* Prolift Report [Dkt. 4328-2] at 11-12 (Gynemesh PS), 16-17 (Prolift), 27-28 (Prolift+M), 30-31 (Prosima), 37-40 (responding to Plaintiffs’ experts’ design defect theories); TVT Report [Dkt. 4328-3] at 8-9 (Prolene generally), 9-10 (TVT and TVT-O), 14-15 (TVT Abbrevio), 16 (TVT Exact), 24-28 (responding to Plaintiffs’ experts’ design defect theories).

This conflation of the term “design” is now a standard practice for Plaintiffs in this MDL. They persist in this manner despite the Court providing unambiguous “clarification” and rejection of Plaintiffs’ contentions about this issue:

At first glance, it seems the plaintiffs want to prevent Dr. Anhalt from providing any opinions that even mention the word “design.” But the mere utterance of a single word is not an incantation that transforms an opinion about one thing into something else.

A close, contextual reading of the transvaginal mesh cases where this issue has been raised before reveals the heart of the plaintiffs’

objections. In this motion—and several others—the plaintiffs argue that the expert at issue lacks the particularized skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-marketing product testing and product development. But upon review, I find Dr. Anhalt has not expressed any opinions about the process of designing a product.

*In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, Mem. Op. & Order (*Daubert* Motion re: Melvin Anhalt, M.D.), 2016 WL 4493585, at \*3 (S.D. W. Va. Aug. 25, 2016).

Like Dr. Anhalt, Dr. Shoemaker does not opine about the design process employed by Ethicon in developing the subject devices. *See generally* Prolift Report [Dkt. 4328-2]; TVT Report [Dkt. 4328-3]. Plaintiffs’ arguments that Dr. Shoemaker’s “design” opinions should be excluded because he lacks the necessary qualifications to discuss the design process are wholly misplaced, and the Court should deny Plaintiffs’ Motion.

**B. Dr. Shoemaker Is Imminently Qualified to Offer His Opinions About the Physical Properties of the Mesh and Its Interaction with the Human Body**

Those opinions of Dr. Shoemaker that Plaintiffs mischaracterize as “design” opinions are his opinions about the physical properties of the mesh and how those properties operate *in vivo*. For example, Dr. Shoemaker opines that the “clinical data” demonstrates that Prolene pelvic mesh is biocompatible, has a minimal inflammatory response, and allows for adequate tissue growth. Prolift Report [Dkt. 4328-2] at 37. Likewise, he found that the data shows that Prolene is not associated with a significantly increased risk of infection as compared to vaginal surgery in general. *Id.* Also, he opines that there is no data to suggest that Prolene is cytotoxic or causes adverse inflammatory responses, sarcoma, or cancer. *Id.* In support of these opinions, Dr. Shoemaker discusses the medical literature and his own clinical experience with the products. *See id.*

Plaintiffs challenge Dr. Shoemaker's qualifications to opine on the physical properties of the devices, erroneously contending that expert testimony cannot be based on clinical experience. *See* Pls.' Br. [Dkt. 4329] at 17-18. This is directly contrary to this Court's prior holdings.

Repeatedly, this Court has held that surgeons who have extensive experience implanting these devices are qualified to opine regarding how the mesh interacts with the human body.

Dr. Anhalt has . . . performed or participated in over 2,000 surgeries using TVT or related mesh. He is a board-certified urologist and clinical instructor who has trained surgeons on mesh procedures. This extensive clinical experience, combined with a review of peer-reviewed literature, qualifies Dr. Anhalt to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products. The plaintiffs' Motion is DENIED on this point.

*See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4493585, at \*3.

The plaintiffs seek exclusion of Dr. Bales's testimony about whether or not clinical data and evidence indicate that mesh degrades, is cytotoxic, is biocompatible, or causes an inflammatory response. . . . The lack of engineering expertise does not render Dr. Bales unqualified to offer these opinions, particularly because he intends to opine only on the clinical aspects of these characteristics. Dr. Bales has performed thousands of pelvic mesh procedures and treated patients experiencing complications. . . . This extensive clinical experience, combined with his review of peer-reviewed literature, qualifies Dr. Bale to opine on mesh's reaction to and effect on the human body. The plaintiffs' Motion on this matter is DENIED.

*In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, Mem. Op. & Order (*Daubert* Mot. re: Gregory T. Bales, M.D.), MDL No. 2327, 2016 WL 4493660, at \*3 (S.D. W. Va. Aug. 25, 2016)

Similarly, Dr. Shoemaker's opinions about the properties of the mesh come from his decades of experience implanting thousands of the subject devices, *see* Prolift Report [Dkt. 4328-2] at 2-3; TVT report [Dkt. 4328-3] at 2-3. as well as his extensive review of the medical literature. The Court has repeatedly found the opinion testimony of gynecologists with similar backgrounds to be admissible.

**IV. Dr. Shoemaker’s Methodology Used to Arrive at His Opinions About the Physical Properties of the Devices Is Reliable.**

**A. Plaintiffs Identify Nothing “Inappropriate” About Dr. Shoemaker’s Literature Review.**

Plaintiffs contend that Dr. Shoemaker’s literature review was not “appropriate.” Pls.’ Br. [Dkt. 4329] at 13. As an initial matter, Plaintiffs appear to agree that a literature review can serve as a reliable method to arrive at an opinion regarding how Prolene interacts with the human body. *See id.* at 13. In fact, this Court has previously found a literature review to be a reliable methodology:

[T]he plaintiffs challenge the reliability of Dr. Fleischmann’s opinions that degradation, shrinkage, and contraction do not occur, or do not occur in any clinically significant manner. Dr. Fleischmann’s opinions are based on her review of the medical literature, which she discusses in detail in her expert report, and her corroborating clinical experience. Dr. Fleischmann appears to be relying primarily on her review of the relevant literature. The plaintiffs claim she “ignored” contrary literature, yet Ethicon explains why the allegedly contrary literature was not relevant or relied upon by Dr. Fleischmann. The plaintiffs’ concerns about Dr. Fleischmann’s literature review are better suited for cross-examination. In this instance, I find sufficient indicia of reliability for Dr. Fleischmann’s opinions on the material properties of mesh. The plaintiffs’ Motion is DENIED on this matter.

*In re: Ethicon, Inc. (Daubert Motion re: Nicole Fleischmann)*, MDL No. 2327, 2016 WL 4547049, at \*3 (S.D. W. Va. Aug. 31, 2016).

It is unclear what Plaintiffs contend is “inappropriate” about Dr. Shoemaker’s literature review. Only two points can be gleaned from their Brief: (1) they object to Dr. Shoemaker citing studies that report on outcomes for a time period of 24 months or less, *see* Pls.’ Br. [Dkt. 4329] at 14, and (2) they object to his citing four “abstracts” as opposed to the articles, *see id.* Neither argument is availing.

**1. Dr. Shoemaker's Reliance on Articles Reporting on Outcomes of Less than 24 Months Goes to Weight, Not Admissibility**

Plaintiffs' argument that all studies with less than a 24 month follow-up period are unreliable is an invented criterion that has no basis in the law. Among the literally hundreds of articles reviewing transvaginal mesh, two authors have suggested that 24 months should be the minimal postoperative follow-up period. This 24-month theory is not a recognized standard among practitioners or researchers. *See generally* Reliance List [Dkt. 4328-6] (Khandwala – study in 2013 reporting on one-year outcome, Quemener – study in 2014 reporting on median follow-up of 20 months).

Second, while some of the studies relied upon by Dr. Shoemaker report on outcomes at less than 24-months, many others report on outcomes well beyond Plaintiffs' arbitrary 24-month window. *See generally* Reliance List [Dkt. 4328-6] (Angioli – 5 year results, Groutz – 10 year outcome, Laurikinen – 5 year results, Liapis 5- and 7-year follow-up, Nilsson – 5 year data, Nilsson – 11 year data, Sertait – 10 year outcome, etc.).

The fact that Dr. Shoemaker disagrees with Plaintiffs' self-invented 24-month criteria and/or that he relies on some studies that evaluate outcomes at less than 24 months in conjunction with studies that evaluate outcomes beyond 24 months goes to the weight, not admissibility, of Dr. Shoemaker's opinions.

**2. Dr. Shoemaker's Reliance on Four Abstracts Does Not Undercut the Reliability of His Methodology**

Plaintiffs' argue that Dr. Shoemaker's physical properties opinions are unreliable because he "relied heavily on 'abstracts' of medical literature, as opposed to full peer-reviewed and published articles." This contention is also without a factual or legal basis.

During Dr. Shoemaker's deposition, Plaintiffs identified four abstracts upon which he relied in arriving at his opinions. One was a follow-up to an earlier article; another was an

abstract of an oral presentation. Dr. Shoemaker's reliance list includes more than 900 articles that he reviewed and relied upon in reaching his opinions. *See generally* Reliance List [Dkt. 4328-6]. That 4 among 900 were abstracts, does not render his opinions unreliable.

Second, there is no indication that Dr. Shoemaker "relied heavily" on abstracts versus articles as Plaintiffs argue. The testimony indicates that Dr. Shoemaker did not "rely heavily" on abstracts. To the contrary. Dr. Shoemaker specifically testified that the Cochrane meta-analyses served as his most prominent reliance material. *See* Shoemaker 07/21/17 Depo. [Dkt. 4328-4] 21:16-21:20 (stating a meta-analysis is "the highest level of studies that we have that I rely on"), 233:1-233:10 (describing his reliance on the Cochrane meta-analysis and referring to the Cochrane review as the "pinnacle" on the "pyramid of evidence").

**C. Dr. Shoemaker's Reliance on His Clinical Experience and Literature Review Are Sufficiently Reliable to Arrive at the Opinion that Polypropylene Is Not Cytotoxic**

Plaintiffs again argue that Dr. Shoemaker cannot rely upon his clinical experience to arrive at any opinions. *See* Pls.' Br. [Dkt. 4829] at 17. For the reasons discussed above, this is an incorrect statement of the law.

**D. Dr. Shoemaker's Reliance on His Clinical Experience and Literature Review Are Sufficiently Reliable to Arrive at the Opinion that Degradation of Prolene, if Any, Is Not Clinically Significant**

Plaintiffs argue that Dr. Shoemaker cannot opine on degradation. *See* Pls.' Br. [Dkt. 4329] at 18. Here, Plaintiffs misrepresent Dr. Shoemaker's opinions. Plaintiffs argue that Dr. Shoemaker is attempting to opine that degradation of Prolene is "impossible." *See id.* at 19. That is not what Dr. Shoemaker opines. Rather, he states that in his clinical experience and based upon his review of the medical literature, degradation (if it occurs) does not have any clinical significance. *See* Prolift Report [Dkt. 4328-2] at 39.

Dr. Shoemaker's clinical experience dealing with thousands of patients who have been implanted with these devices coupled with the medical literature demonstrating the lack of clinical significance of alleged degradation are sufficiently reliable to render his opinion that degradation (if it occurs) has no clinically significant effect. *See id.* at 39.

### **CONCLUSION**

For the above reasons, Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson respectfully request that this Court enter an order denying Plaintiffs' Motion to Exclude or Otherwise Limit the Opinions and Testimony of Defense Expert Marshall Shoemaker, M.D. [Dkt. 4328].

Respectfully submitted,

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
(601) 948-5711  
Christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)  
Thomas Combs & Spann PLLC  
300 Summers Street  
Suite 1380 (25301)  
P.O. Box 3824  
Charleston, WV 25338  
(304) 414-1807  
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS ETHICON, INC.,  
ETHICON, LLC, AND JOHNSON & JOHNSON

**CERTIFICATE OF SERVICE**

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/Christy D. Jones